REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-8, 13-15, and 18 are currently under consideration. Claims 1-5, 7, 8, 13-15, and 18 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter has been added.

Support for amended claims 1-3, 8, 13-15, and 18 can be found, as an example, on page 18, lines 1-3 and 15-23. Support for the amendment to claims 4 and 5 can be found, for instance, on page 5, lines 21-31.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 1 was rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and claim the subject matter which Applicant regards as the invention. This rejection is respectfully traversed.

Specifically, the Office Action contends that, in claim 1, there is nothing linking the two compositions, and requires further specification of how these two compositions are admixed or combined.

In response, Applicant draws attention to the amendment to claim 1, which herein recites "a **kit** comprising a first pharmaceutical composition..." (emphasis added). It is noted that this amendment was suggested by the Examiner in the Office Action. More importantly, claim 1 fulfills the Office Action's request to describe the first and second compositions prior to administration.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §102(b) ARE OVERCOME

Claims 1-3, 13-15, and 18 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Lang et al. (U.S. Patent No. 5,506,112; hereinafter "Lang"). According to the Office Action, Lang teaches a method of adding a mixture of factor IXa and phospholipids to a sample containing factor VIII, wherein activated factor VIII forms a complex with factor IXa. Applicant respectfully traverses this rejection.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U .S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue,* 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

With this in consideration, Applicant respectfully argues that Lang does not contain all of the elements of the claim invention. Applicant notes that the amendment to claim 1 clarifies the invention as comprising a first and second **pharmaceutical** composition. Importantly, Lang does not teach, or even suggest, a kit comprising **pharmaceutical compositions** (claims 1-3), a method comprising mixing together coagulation factors VIII and IXa into a **pharmaceutical composition** (claims 13-15), or the **pharmaceutical composition** as described in claim 18. Instead, Lang is directed to a reagent "to be used both for assaying body liquids as to their factor VIII activities and for automatically examining highly purified factor VIII preparations" (column 1, lines 59-63). Thus, Lang does not anticipate claims 1-3, 13-15, and 18.

Claims 4-8 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Capon et al. (U.S. Patent No. 4,965,199; hereinafter "Capon"). The Office Action asserts that Capon teaches a method for producing factor VIII in recombinant mammalian host cells, and further alleges that Capon teaches that factor VIII is capable of catalyzing the conversion of

factor X to Xa in the presence of factor IXa, calcium, and phospholipids, and therefore is able to correct the coagulation defect in plasma derived from hemophilia A-affected individuals.

In response, Applicant notes the amendment to claim 4, which clarifies that the method of treating haemophilia A or B comprises administering to a **patient** the disclosed pharmaceutical composition. With this amendment in mind, Capon does not teach each and every element of the invention of claim 4. Capon is directed to a method for producing factor VIII in recombinant mammalian host cells, and does not teach or suggest the administration of a pharmaceutical composition consisting essentially of coagulation factors VIII **and** IXa to a **patient**.

Furthermore, Capon does not teach or suggest a method of administering this composition wherein the presence of coagulation factor IXa allows the concentration of coagulation factor VIII in the composition to be reduced. Figure 1 of Capon, as referenced by the Office Action, does not account for the decrease in concentration of Factor VIII **in the composition** due to the presence of factor IXa; rather Figure 1 refers to the coagulation cascade, which is in the presence of the other factors and components found in blood. Therefore, Capon does not anticipate claim 4, nor dependent claims 5-8.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) are respectfully requested

IV. THE OBJECTION TO THE CLAIMS ARE OVERCOME

Claim 13 is objected for not reciting the term "factor" after the term "coagulation" in line 1. Applicant notes that Claim 13 is amended herein such that claim 13 presently recites "a method for potentiating coagulation factor VIII comprising..."

Accordingly, reconsideration and withdrawal of the objection to the claims are respectfully requested

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and her SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

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